HPE-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
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August 30, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
CIN-WL-00-1584

Mr. James J. Betz
Chief Operating Officer
Betco Corporation, Ltd.
1001 Brown Avenue
Toledo, OH 43607

Dear Mr. Betz:

This letter concerns the manufacturing and marketing of over-the-counter (OTC) drug products by your firm. During an inspection of your facilities beginning on December 16, 1999, and ending on January 14, 2000, our investigator obtained immediate container labels, promotional labeling, and formulation information for the following OTC drug products:

"WINNING HANDS PREMIUM ANTIBACTERIAL HAND CLEANER"
"WINNING HANDS Pearlized Antiseptic Lotion Hand Cleaner"
"WINNING HANDS SANI-GEL"
"WINNING HANDS E-2 Food Industry Hand Cleaner"

Based on their respective labels and labeling, these products are intended to kill or reduce the number of microorganisms on the skin and thereby prevent diseases that may be caused by those organisms. Thus, these products are "drugs" as defined by Section **201(g)** of the Federal Food, Drug, and Cosmetic Act (the Act).

From the information and labeling obtained during our inspection, these products violate the new drug application and misbranded drug provisions of the Act as described below.

Since the respective labeling for the above named drug products fails to differentiate between active and inactive ingredients, all listed ingredients are represented as active drug ingredients. We are not aware of any data demonstrating that the respective labeled combinations of ingredients are generally recognized by experts as safe and effective for any topical antimicrobial use. In fact, except for "Isopropyl Alcohol," identified on the labeling for **"WINNING HANDS SANI-GEL,"** none of the labeled ingredients in any of the other products named above is covered by FDA's ongoing OTC Drug Review for any antimicrobial use.

Thus, these products are "new drugs," as defined by section **201(p)** of the Act. Because none of the products has an FDA-approved new drug application, as described under section **505(b)** of the Act, the marketing of these products in the United States violates section **505(a)** of the Act.

These products are misbranded under section **502(f)(1)** of the Act, because the adequacy of the labeled directions for antimicrobial use has not been established through an approved NDA. These products are also misbranded under section **502(o)** of the Act, because they have not been listed with FDA as required by section **510** of the Act.

A number of product-specific violations of the Act and a discussion of those violations follow:

"WINNING HANDS PREMIUM ANTIBACTERIAL HAND CLEANER"

As noted above, the labeling represents this product as useful in killing or reducing the number of bacteria on the skin. The labeling for this product specifically claims effectiveness against "Staphylococcus aureus - MRSA [Methicillin-Resistant Staphylococcus Aureus]," "Staphylococcus aureus," "Salmonella typhimurium," "Enterococcus faecalis - VRE [Vancomycin-Resistant Enterococcus]," "Pseudomonas aeruginosa," and "Escherichia coli 0157:47." By naming these bacteria within the context of claims for antimicrobial effectiveness, the labeling suggests that the product is useful in preventing the diseases caused by them. Such representations and suggestions further cause this product to be a "new drug" under section **201(p)** of the Act, because we are not aware of any scientific data showing that it is generally recognized as safe and effective for these uses. Since this product is not the subject of an approved NDA and the adequacy of the directions for these uses has not been established under an NDA, it further violates sections **505(a)** and **502(f)(1)** of the Act.

Based on information and records supplied during the inspection noted above, this product contains the color additive "[redacted] Orange Dye (Acid)." Since we are not aware of any information showing that this color additive is safe under section **721(a)** of the Act, its presence in the formulation also causes the product to be a "new drug" and further violates sections **505(a)** and **502(f)(1)** of the Act.

We acknowledge receipt of a proposed revision to the immediate container label for this product, which you provided our investigator at the conclusion of the inspection. That revision consists only of adding the heading "ACTIVE INGREDIENTS" followed by "Chloroxylenol 0.5%." Your proposed revision does not, however, remedy the "new drug" [section **505(a)**] and misbranding [section **502(f)(1)**] violations resulting from: (1) representations in the labeling that the product is useful in preventing diseases caused by certain specific microorganisms named in the labeling, and (2) resulting from the presence of the unsafe color additive, as described above. The proposed revision also fails to address the drug listing violation [section **502(o)**] noted above.

"WINNING HANDS Pearlized Antiseptic Lotion Hand Cleaner"

Based on information and records supplied during the inspection noted above, this product contains the color additive "[redacted] Green Dye." Since we are not aware of any information showing that this color additive is safe under section **721(a)** of the Act, its presence in the formulation also causes the product to be a "new drug" and further violates sections **505(a)** and **502(f)(1)** of the Act.

At the conclusion of the inspection, you provided our investigator with a proposed revision to the immediate container label for this product. That revision consists only of adding the heading "ACTIVE INGREDIENTS" followed by "Chloroxylenol .375%." Your proposed revision does not, however, remedy the "new drug" [section **505(a)**] and misbranding [section **502(f)(1)**] violations resulting from the presence of the unsafe color additive described above. The proposed revision also fails to address the drug listing violation [section **502(o)**] noted above.

"WINNING HANDS SANI-GEL"

This product is also misbranded under section **502(e)(1)(A)(ii)** of the Act, since the labeling fails to disclose the quantity of isopropyl alcohol.

The proposed revision to the immediate container label, which you provided our investigator at the conclusion of the inspection, consists only of adding the heading "ACTIVE INGREDIENTS" followed by "Isopropanol 55%." Since this proposed revision does not declare the "ACTIVE INGREDIENT" by its established name, i.e. "Isopropyl Alcohol," the product remains misbranded under section **502(e)(1)(A)(ii)** of the Act. Your proposed revision also fails to address the drug listing violation [section **502(o)**] noted above.

"WINNING HANDS E-2 Food Industry Hand Cleaner"

From information obtained during the inspection, this product contains as its active drug ingredient [redacted] a concentration of [redacted]. This concentration causes the product to be a "new drug" under section **201(p)** of the Act, because we are not aware of any scientific data showing that it is generally recognized as safe and effective for the OTC antimicrobial uses described in the labeling. FDA is also not aware of such a concentration for these uses having ever been marketed in the United States to qualify for evaluation under the agency's OTC Drug Review. Since this product is not the subject of an approved NDA and the adequacy of the directions for these uses have not been established under an NDA, it further violates sections **505(a)** and **502(f)(1)** of the Act.

This product is also misbranded in that the labeling fails to declare the active drug ingredient by its established name, i.e., "[redacted]," as required by section **502(e)(1)(A)(ii)** of the Act.

The proposed revision to the immediate container label for this product, which you provided our investigator at the conclusion of the inspection, consists only of adding the heading "ACTIVE INGREDIENTS" followed by "[redacted]%." Your proposed revision does not, however, remedy the "new drug" [section **505(a)**]and misbranding [section **502(f)(1)**] violations resulting from the concentration of the active antimicrobial drug ingredient, benzalkonium chloride, as described above.

Your proposed revision continues to identify the active drug ingredient in the list of "OTHER INGREDIENTS" as "Quaternary Ammonium Chloride." Since this is not the established name for this ingredient, as noted above, the product remains misbranded under section **502(e)(1)(A)(ii)** of the Act. In addition, the proposed revision does not remedy the drug listing violation [section **502(o)**] noted above.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may take this information into account when considering the award of contracts. We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice and may include seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations described above. It should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Stephen Rabe, Compliance Officer, at the above letterhead address.

Sincerely,

Carol A. Zoppe

for Henry L. Fielden,
District Director

cc: Paul C. Betz, President